

## REMARKS

The final Office Action mailed February 9, 2005 has been received and carefully reviewed. Claims 1-17 and 24-31 stand rejected in the application. Claims 18-23 were previously cancelled, without prejudice. Reconsideration of the application in view of the following remarks and withdrawal of the finality of the rejections are respectfully requested.

On page 18 of the final Office Action, the Examiner indicates that Applicant's arguments with respect to claims 1-17 and 24-31 presented in the prior responsive communication have been considered but are moot in view of the new grounds of rejections. Applicant has carefully considered the Examiner's new grounds of rejection and respectfully asserts that such new grounds for rejecting Applicant's claims are overcome by the following arguments. Applicant has not amended the claims in response to the final Office Action.

Claims 13-17 and 24-31 stand newly rejected under 35 U.S.C. § 112, first paragraph with regard to the written description requirement. Applicant respectfully asserts that the specification provides the requisite written description of the subject matter recited in claims 13-17 and 24-31. By way of example, Applicant makes reference to page 9, lines 16-29 of Applicant's specification, which is reproduced below, with emphasis added, for the Examiner's convenience:

A guide catheter according to the present invention will generally be used to assist in implanting the payload 107 into a cardiac destination vessel. In one aspect of the present invention, the inner guide 100 is more compliant than the outer guide 101. A relatively rigid outer guide 101 is beneficial during insertion as it helps to prevent kinking and allows better transmittal of pushing forces. The inner guide 100 is commonly more flexible to afford greater maneuverability within a constricted heart chamber.

When a catheter embodying aspects of the present invention is advanced through the venous pathways, the inner guide 100 can be retracted within the outer guide 101. The inner guide 100 is relatively compliant compared to the outer guide 101, so the inner guide 100 tends to assume the shape of the outer guide 101 when retracted. Once the distal tip of the outer guide 101 has located a chamber of the heart, such as the right atrium, the flexible inner guide 100 is then extended from the distal end of the outer guide 101.

Applicant respectfully requests the Examiner to withdraw the rejection of claims 13-17 and 24-31 under 35 U.S.C. § 112, first paragraph. Confirmation of same is respectfully solicited in the Examiner's next official communication.

Numerous Section 35 U.S.C. 103(a) rejections were presented in the Final Office Action, as follows:

Claims 1, 5-9 and 11-12 stand rejected over Norlander et al. (of record) in view of Dubrul (of record) and in further view of Gould et al. (of record); claims 2-4 stand rejected over Norlander, Dubrul and Gould as applied to claim 1 above, and in further view of Wells (of record); claim 10 stands rejected over Norlander, Dubrul and Gould as applied to claim 1 above, and in further view of Schaer (of record); claims 13, 17, 24-27 and 29-31 stand rejected over Norlander, Dubrul and Gould as applied to claim 1, and in further view of Williams et al. (U.S. Patent 6,408,214); claims 14-16 stand rejected over Norlander, Dubrul, Gould and Wells as applied to claim 2-4 above, and in further view of Williams; and claim 28 stands rejected over Norlander, Dubrul and Schaer as applied to claim 10 above, and in further view of Williams.

Initially, Applicant reasserts the arguments made in the previous responsive communication concerning the patentability of Applicant's claims. For purposes of brevity, these arguments will not be reiterated hereinbelow, but are supplemented by the following additional arguments that specifically address the Examiner's new grounds of rejection.

To establish *prima facie* obviousness of a claimed invention, the Examiner has the burden of proving that three basic criteria are met. First, there must be some suggestion or motivation to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicants' disclosure. All three of these criteria must be met in

order to support a finding of *prima facie* obviousness of a claimed invention (see, e.g., MPEP § 2142).

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the Applicant is under no obligation to submit evidence of nonobviousness. MPEP § 2142. Applicant respectfully submits that mischaracterizations of the asserted references and combinations thereof presented in the final Office Action, as discussed below, have resulted in the failure to factually support the Examiner's *prima facie* conclusion of obviousness.

Respectfully, the Examiner has erroneously characterized the Dubrul structure and the proposed modification of Norlander's guide handle in view of the Dubrul structure. The splittable sheath 80 taught in Dubrul is not an outer guide of a catheter, nor is the splittable sheath 80 connected to the guide handle of the catheter. Rather, Dubrul describes splittable sheath 80 as being removable and of a length that will cover approximately half of the access tube 72 in its axially elongated configuration (e.g., stretched condition). Column 7, line 51 through column 8, line 2.

Concerning the rejection of claims 1, 5-9 and 11-12 over Norlander in view of Dubrul and in further view of Gould, Applicant respectfully asserts that this asserted combination of references fails to teach or suggest all the claim limitations recited in the subject claims. For example, the asserted combination fails to teach a guide catheter having a splittable outer guide connected to a splittable guide handle.

On page 3 of the final Office Action, the Examiner acknowledges that Norlander fails to disclose a guide handle having a distal end connected to a proximal end of the outer guide. On page 4 of the final Office Action, the Examiner contends that it would have been a matter of obvious design choice to have modified Norlander's guide handle so as to have a distal end connected to the proximal end of the outer guide as taught by Dubrul, as an equivalent alternative. Applicant makes reference to the

mischaracterization of the Dubrul teachings and, therefore, to the asserted combination of Norlander and Dubrul.

The addition of Gould to the combination of Norlander and Dubrul still fails to teach or suggest the elements clearly missing in the Norlander/Dubrul combination. Gould, for example, fails to teach a splittable outer guide or a splittable handle connected to a splittable outer guide.

Clearly, *prima facie* obviousness of Applicant's claims 1, 5-9 and 11-12 has not been established, as the asserted combination of Norlander, Dubrul, and Gould fails to teach or suggest all elements of Applicant's claims 1, 5-9 and 11-12.

Further, Applicant respectfully asserts that the combination of Norlander, Dubrul, and Gould lacks the requisite motivation to support their combination in a manner suggested by the Examiner. The Examiner appears to have picked out certain features recited in Applicant's claims found in various forms in several prior art references without articulating how these reference teachings provide the requisite motivation or suggestion to support their combination. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

On page 5 of the final Office Action, the Examiner contends that it would have been obvious to have modified Norlander in view of Dubrul's guiding catheter with the steering mechanism as taught by Gould. Respectfully, the Examiner has again mischaracterized the Dubrul device as a guiding catheter. The Dubrul device is not a guiding catheter and is devoid of a steering mechanism. The Dubrul device is an apparatus for introducing and anchoring an access tube through a tissue penetration in a patient's body. This tube can be used for drainage and feeding (Dubrul, column 3, lines 1-6).

Moreover, Applicant respectfully asserts that the Examiner's proposed modification of the Norlander device by the steering mechanism as taught by Gould

would change the principle of the steering operation of the Norlander device. Norlander teaches an additional steerage member, such as a dilator 27, obturator, or deflecting tip device 74, which is placed within the passageway of the sheath for assisting with introduction and placement of the introducer sheaths 11, 12 (see, e.g., column 7, line 36 through column 8, line 43 and column 9, lines 1-40). Gould teaches a steering mechanism that employs a pull wire situated within a tubular body of the catheter which is coupled to the distal end of the body's flexible tip. Pulling on the wire causes the tip member to bend (see, e.g., Abstract). One skilled in the art will readily appreciate the significant differences between the Norlander and Gould steering operations.

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Applicant respectfully asserts that the proposed modification of the Norlander device by the steering mechanism as taught by Gould would change the principle of the steering operation of the Norlander device.

Because the combination of Norlander, Dubrul, and Gould fails to teach or suggest several of the above-identified limitations and because no motivation or suggestion to combine the references can be identified in the references themselves, Applicant respectfully asserts that the Examiner has failed to establish *prima facie* obviousness of Applicant's subject matter recited in claims 1, 5-9 and 11-12. Applicant respectfully asserts that independent claim 13 and all other dependent claims are patentable over the various combinations involving Norlander, Dubrul, and Gould for the same reasons presented above. As such, Applicant respectfully asserts that the Examiner has failed to establish *prima facie* obviousness of Applicant's subject matter recited in claims 2-4, 10, 13-17, and 24-31.

While Applicant does not acquiesce with any particular rejections to the remaining dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1 and 13. These dependent claims include all of the limitations of the base claim and any intervening claims, and

recite additional features which further distinguish these claims from the cited references. "If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious." M.P.E.P. §2143.03; citing *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Therefore, dependent claims 2-12 and 14-17 are also allowable over the asserted combination of references.

Applicant respectfully asserts that the several obviousness-type double patenting rejections set forth in the Office Action are now moot in view of the remarks presented above. As to the several provisional obviousness-type double patenting rejections set forth in the Office Action, Applicant respectfully refers to MPEP § 804 I(B) which provides:

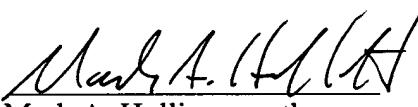
The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications. If the "provisional" double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent. Emphasis added.

Applicant respectfully asserts that, in view of the arguments made above, the Examiner is compelled to withdraw the substantive art rejections of the claims. Once withdrawn, the only rejection remaining in the subject application is the provisional obviousness-type double patenting rejection. In view of MPEP § 804 I(B), Applicant respectfully requests that the provisional obviousness-type double patenting rejection be withdrawn and that the subject application be permitted to issue as a patent.

It is believed that the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if there are any questions regarding the above new claims or if prosecution of this application may be assisted thereby.

Respectfully submitted,  
Crawford Maunu PLLC  
1270 Northland Drive, Suite 390  
St. Paul, MN 55120  
(651) 686-6633 x104

Date: April 11, 2005

By:   
Mark A. Hollingsworth  
Reg. No. 38,491